December 07, 2004

Office of Special Nutritionals (HFS-450) Center for Food Safety and Applied Nutrition Food and Drug Administration 200 C St. SW., Washington, D.C. 20204

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RE: Notification of Nutritional Support Statements

To whom it may concern:

I hereby notify the Food and Drug Administration (FDA) of the use of statements of nutritional support in the labeling of CoenzymatedTM B-6, a dietary supplement. Source Naturals[®] is the manufacturer of CoenzymatedTM B-6.

Statements being made in the labeling of CoenzymatedTM B-6

- 1) In order for vitamins to be utilized by the body, they must first be converted into their active coenzymated forms.
- 2) This more potent coenzymated B-6 is in its active form and ready to go to work immediately.
- 3) Pyridoxal-5'-Phosphate (PLP or P-5'-P) is the main metabolically active coenzyme form of vitamin B-6.
- 4) It is primary in the liver that P-5'-P is synthesized from pyridoxine, with the help of enzymes that require B-2, zinc and magnesium for their activity.
- 5) P-5'-P activates over 100 enzymes, many of which are involved in the conversion of amino acids into the neurotransmitters dopamine, norepinephrine and serotonin.
- 6) P-5'-P is also required for the synthesis of the hemoglobin molecule and plays an important role in regulating homocysteine levels.

To the best of my knowledge and belief, and based upon information available at the time of the execution of this notice, I certify that the above information is accurate and complete. Source Naturals® possesses substantiation that the statements are truthful and not misleading.

Ira L. Goldberg

President, Source Naturals®

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